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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,016	03/24/2001	Mark B. Lyles	068986.0107	5726

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/817,016	Applicant(s) LYLES, MARK B.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-41, 43-48 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) 19-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43-48, 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-41, 43-48 and 56-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 41, 43-48, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) in view of Koester et al. (US Pat. 4,923,901).

Yasukawa et al. teach a porous matrix and methods of its production. Fused fibrous ceramic materials are prepared from amorphous silica and/or alumina fibers with 2 to 12% boron nitride. The matrix may be used as a cell culture substrate, an implant material, and for chromatographic separation of blood cells (abstract). The matrix may have a density between 3.5 and 5.5 pounds per cubic foot, and the fibers may have diameters between 0.5 and 20 microns, with a diameter of between 0.5 and 5 microns in one of the preferred embodiments. For use as an implantable material, the matrix may be coated with a biocompatible material on its outer surface. For use in affinity chromatography, the fibers may be derivatized with molecules

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effective to bind ligand molecules passed through the matrix (Col. 1). Since alumina is an optional component of the matrix, it is inherent that silica may form greater than 50% of the surface of the matrix. However, the reference does not teach the use of specific biological compounds linked to the material.

Koester et al. teach membranes with bound oligonucleotides and peptides. The reference teaches that nucleic acids or peptides/proteins may be either adsorbed or non-specifically linked to materials such as porous alumina or silica. In addition, the reference teaches that nylon or nitrocellulose are often used to immobilize nucleic acids by adsorption.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize nucleic acids or peptides/proteins as taught by Koester et al. with the method of Yasukawa et al. because Koester et al. teaches that these molecules may be linked to surfaces of silica or alumina. In addition, Yasukawa et al. contemplate the linking of biological materials to the surfaces of their invention. Further, although Koester does not specifically teach linking of molecules to surfaces of alumina, silica, and a fusion source, one of skill in the art would have known that the chemistry involved in linking molecules to that type of surface would be very similar to that of alumina or silica alone, and would have required only routine optimization. Koester et al. teach that biological molecules may be linked to alumina or silica, which would have given one a reasonable expectation of success in doing the same with a material composed of both alumina and silica. Also, the boron fusion source may comprise as little as 2% of the total surface of the material, which would not materially affect the surface chemistry for immobilization purposes. Furthermore, although Yasukawa does not specify the exact percentages of alumina or silica as between 1-50% and 50-98% respectively, such would

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have been obvious to one of ordinary skill at the time of the invention because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In addition, it would have been obvious to make a material with a density of 6 pounds per cubic foot because Yasukawa teaches a density of up to 5.5, and one would have had a reasonable expectation of success in making a material that is only a little denser because there is no reason to believe that a half-pound increase in density would adversely affect the device in any way.

4. Claims 41, 43-48, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle et al. (WO 96/24631) in view of Koester et al. (US Pat. 4,923,901).

Lyles et al. teach dental materials comprising from about 1-50% by weight alumina, 50-90% by weight silica, and 1-5% by weight boron. In preferred embodiments, the composition may have 2.85% boron nitride. The mean pore diameter of the material is greater than 10 microns (page 20). The density of the material may be from 4-62 pounds per cubic foot (page 5). According to the reference, silanization improves the fiber to resin bond. However, the reference does not teach the use of specific biological compounds linked to the material.

Koester et al. teach membranes with bound oligonucleotides and peptides. The reference teaches that nucleic acids or peptides/proteins may be either adsorbed or non-specifically linked to materials such as porous alumina or silica. In addition, the reference teaches that nylon or nitrocellulose are often used to immobilize nucleic acids by adsorption.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize nucleic acids or peptides/proteins as taught by Koester et al. with the method of Lyles et al. because Koester et al. teaches that these molecules may be linked to

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surfaces of silica or alumina. In addition, although Koester does not specifically teach linking of molecules to surfaces of alumina, silica, and a fusion source, one of skill in the art would have known that the chemistry involved in linking molecules to that type of surface would be very similar to that of alumina or silica alone, and would have required only routine optimization. Koester et al. teach that biological molecules may be linked to alumina or silica, which would have given one a reasonable expectation of success in doing the same with a material composed of both alumina and silica. Also, the boron fusion source may comprise as little as 2% of the total surface of the material, which would not materially affect the surface chemistry for immobilization purposes.

Response to Arguments

5. Applicant's arguments filed 6/15/04 have been fully considered but they are not persuasive.
6. Applicant first asserts that the cited references fail to disclose every element of the claims but has provided no basis or rationale for this position, which renders the argument *prima facie* unconvincing. Applicant's argument amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references and does not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. See 37 CFR 1.111(b)(c).
7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

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teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art at the time of the invention would have been motivated to immobilize nucleic acids or peptides/proteins as taught by Koester et al. with the method of Yasukawa et al. or Lyles et al. because Koester et al. teaches that these molecules may be linked to surfaces of silica or alumina. In addition, Yasukawa et al. contemplate the linking of biological materials to the surfaces of their invention. In terms of the combination of Lyles and Koester,

8. Applicant argues that Koester only mentions the use of alumina or silica on one sentence, but the examiner maintains that this is a sufficient disclosure to provide the motivation to combine the reference with Yasukawa or Lyles.

9. Applicant argues that the Koester reference fails to disclose the combination of alumina and silica, to which the examiner acquiesces; however, Yasukawa as the primary reference was relied upon for that feature, and Koester was only relied upon for teaching the use of specific biological compounds linked to the substrate material.

Conclusion

Claims 41, 43-48, and 56-58 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



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02/05/04